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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,861	12/09/2003	Amy L. Hammack	RADNT-035C	3531

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EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,861

Applicant(s)

HAMMACK ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-52, 54, 56-59 and 62-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-52, 54, 56-59 and 62-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed July 13, 2006 have been fully considered but they are not persuasive. No structure is specifically claimed that would limit or prohibit the temperature sensor from contacting the wall of a blood vessel. The position of the sensor is a function of the use. The applicant discusses, in the background, the desire to measure the blood temperature as opposed to the wall temperature. Such discussion in the **background** indicates this is a known limitation to one of skill in the art. The examiner disagrees that Aliberto et al. do not suggest a deployable sensor. Aliberto et al. discloses the sensor may be disposed in a lumen and attached to a wire with the sensor hanging outside the catheter. A skilled artisan would recognize that the sensor would be deployed after positioning as such an appendage would hinder the insertion of the catheter.

No method step specifically addresses the positioning of the sensor without contact with the vessel wall, nor is such positioning disclosed in the specification.

Heat exchangers for blood are known, as are deployable temperature sensors for blood vessels. A skilled artisan would clearly be motivated to look to alternative temperature measurement techniques within this environment. Diamantopoulos et al., in addition to teaching deployable devices, discloses the differences of temperatures along a diseased wall. While this is key to the intended use of the Diamantopoulos et al. device, it also teaches a potential limitation to other intended uses.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 79 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is dependent on a cancelled claim. (The claim was examined under the assumption it was intended to be dependent on claim 49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-52, 54, 57-59, 62, 65, 66, 71-74 and 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. Aliberto et al. teach a catheter with heat exchange membrane, the catheter body including at least two lumens, and in the preferred embodiment the catheter body includes at least four lumens, two for fluid for temperature control and the others for holding a wire or wires that are attached to one or more distally-located sensors, such as temperature sensors, pressure sensors, gas sensors, and electrical sensors (Col. 4, lines 7-23). The heat exchange areas are disclosed as separate from the temperature sensor (Fig. 1, #s 68 & 100). The sensor is disclosed as a thermistor and can be disposed in a lumen of the catheter, or attached to a wire that is disposed in a lumen of the catheter, with the sensor hanging outside the catheter. This is broadly interpreted as a deployable temperature sensor as a skilled artisan would recognize that any appendage to a catheter would impede insertion of such device. Alternative temperature sensing is also disclosed (Col. 6, lines 27-39). In any case, the sensor is electrically connected to the coolant source for control of the temperature of

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the coolant (Col. 6, line 39) as described in U.S. Patent 6,019,783, incorporated by reference (Col. 3, line 33), which teaches multiple temperature sensors that can be thermistors, thermocouples, RTDs, or other temperature sensing element that can be orally or rectally placed in the patient or that can be mounted on the catheter or otherwise associated with the patient (e.g., the sensor can be an infrared device) to detect a temperature of the patient.

Aliberto et al. does not disclose temperature sensors of nitinol and constrained.

Diamantopoulos et al. teach a catheter for measuring vascular temperature using multiple thermistors (up to 10) on a nitinol (page 14, line 13) support that is resiliently biased (spring) and constrained by a sheath. When the sheath is removed, the thermistor assumes a deployed position. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the thermistors on nitinol supports as taught by Diamantopoulos et al. in the invention of Aliberto et al. as an alternative means for deploying the sensors as one skilled in the art would look to related art for such alternatives. Aliberto et al. teaches measurement of temperatures within a blood vessel as does Diamantopoulos et al. thus establishing a clear link and motivation to look to Diamantopoulos et al.

Regarding claims 53, 65, 66 and 71, a sensor on a wire extendable from a lumen is interpreted as a deployable sensor controllable by an operator. The sensor being so placed would inherently be away from the heat exchange area.

Regarding claims 73 and 74, the disclosure of the sensor in a lumen that may extend out of the catheter inherently adds the step of displacing the sensor out of the catheter as disclosed.

Claims 56, 75 and 77-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. as applied to claims 49 and 73 above, and further in view of U.S. Patent 6,383,144 to Mooney et al. Aliberto et al. and Diamantopoulos et al. are discussed above, but do not teach deployment

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methods or memory materials. Mooney et al. disclose a catheter with a temperature sensor and a method for measuring a temperature, typically, of blood (abstract). Mooney et al. discloses a deployable sensor (Col. 13, line 33), the use of memory metals (Col. 12, line 11) and a self-deployment means (Col. 12, line 14) in a device for measuring the temperature within a vascular structure (Col. 14, line 42). Mooney et al. disclose a thermistor in a tubular probe with the sensor wires within the tubular portion (Fig. 1). The method of use is disclosed as inserting the sensor into a blood vessel and monitoring the temperature via an external device connected by wires to the sensor (Fig. 1). Mooney et al. teach memory metals for the probe and a potting material that releases (from constraint) the probe when within a body allowing the probe to take the shape of the memory material. This provides a self, or automatically, deploying probe. Nitinol is a well-known material for shaped memory. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the memory material and potting technique as taught by Mooney et al. in the device of Aliberto et al. to provide alternative means for deploying a temperature probe without operator activity.

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. as applied to claim 49 above, and further in view of U.S. Patent 6,117,065 to Hastings et al. Aliberto et al. and Diamantopoulos et al. are discussed above, but do not disclose an external lumen. Hastings et al teaches a catheter with an external lumen. The claimed use of an external lumen is not given patentable weight as lumens may be used for many purposes and devices. Further, the position of the temperature probe lumen (internal or external, full or partial length of the catheter) is not disclosed as being critical to its function as confirmed by multiple configurations being claimed in the application. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an external lumen as taught by Hastings et al. in

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the device of Aliberto et al. in view of Diamantopoulos et al. as lumens are pervasive in the art and are well known to be of various sizes, shapes and locations.

Claims 67-70 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,749,585 to Aliberto et al. in view of WO 01/74263 to Diamantopoulos et al. as applied to claims 49, 66 and 73 above, and further in view of WO 94/01177 to Hascoet et al. Aliberto et al. and Diamantopoulos et al. are discussed above, but do not teach a pull wire deployment or a ramp for the deployment of the temperature sensor. Hascoet et al. teach a probe (catheter) having a shaft, an atraumatic tip (Fig. 1, # 551) and a heat exchange region defined by the fluid channels 872 and 874 (Page 14, lines 13-14). A temperature sensor is provided in an integral lumen (Fig. 8, # 892) that is deployable outward from the shaft by either a pull wire (Fig. 8, # 914) or a ramp like sloping member, 916a, to deflect the sensor in the proper direction (Fig. 8, # 916a). It is reasonable to interpret the ramp and probe as having complementary shapes to insure the proper movement of the probe as it is deployed. The sensor is deflected as an operator extends it from the lumen through an opening (aperture) in the side of the shaft. The sensor is disclosed as being deployable to 10 mm and therefore inherently capable of achieving 1.8 to 3.2 mm. Hascoet et al. disclose a fiber optic sensor with the fiber providing temperature information to the proximal end of the probe for control of the flow and/or temperature of the control liquid (Page 5, lines 33-40), strongly implying a closed loop controller for the heat exchange liquid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the deployment techniques as taught by Hascoet et al. in the invention of Aliberto et al. in view of Diamantopoulos et al. as Aliberto et al. clearly suggests temperature sensors spaced from the heat exchanger and Hascoet et al. provides alternative means for positioning of temperature sensors.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

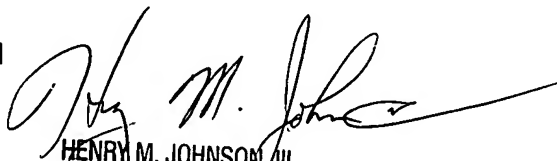
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Henry M. Johnson, III
Primary Examiner
Art Unit 3739



HENRY M. JOHNSON, III
PRIMARY EXAMINER